

# Difficult biliary stones in the elderly: Endoscopic retrograde cholangiography – A single surgical tertiary centre experience with follow-up

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## Abstract

**Background:** Pancreaticobiliary diseases and choledocholithiasis are common in elderly patients. Endoscopic treatment of biliary stones represents a well-established mini-invasive technique. However, limited data are available regarding the treatment of 'difficult' biliary stones, especially in the elderly population. The aim of our study is to evaluate the efficacy and safety of therapeutic endoscopic retrograde cholangiopancreatography (ERCP) in patients  $\geq 85$  years of age with complex biliary stones.

**Materials and Methods:** From January 2015 to January 2017, data from ERCP procedures performed for complex biliary stones were retrospectively collected. The patients were divided into two groups based on their age: Group A – aged 85 years or older ( $n = 110$ ) and Group B – aged 65 years or younger ( $n = 62$ ). Demographic data, success, complications and recurrence rates for both groups were reported.

**Results:** Chronic comorbidities (86.3% vs. 24.2%;  $P < 0.001$ ) and use of antithrombotic drugs (48.2% vs. 19.3%;  $P < 0.001$ ) were more frequent in the elderly. The technical success rate (95.4% vs. 96.7%;  $P > 0.6$ ) and complication rate (8.2% vs. 13%;  $P > 0.2$ ) were not statistically different among the two groups. Periapillary diverticula (PAD) were observed more frequently in Group A (38.1% vs. 17.7%;  $P < 0.006$ ). More patients from Group B underwent cholecystectomy during the same admission (8.2% vs. 42.3%;  $P < 0.001$ ). The recurrence rate was not different among the groups (7.6% vs. 5%;  $P > 0.5$ ). PAD was identified as the risk factor for recurrence ( $P < 0.02$ ).

**Conclusion:** ERCP in the elderly was found to be a safe procedure, carrying a high degree of success for the treatment of difficult biliary stones.

**Keywords:** Difficult biliary stones, elderly, endoscopic treatment, recurrence, therapeutic endoscopic retrograde cholangiopancreatography

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## INTRODUCTION

Pancreaticobiliary diseases, such as cholelithiasis and choledocholithiasis, are common in patients older than 80 years.<sup>[1,2]</sup> In addition, very elderly patients ( $\geq 80$  years) present a large spectrum of comorbidities which make them frail and often unfit for surgery. Surgery is burdened with higher morbidity and mortality in this population.<sup>[3]</sup> Thus, it is important to adopt techniques that are effective in minimising the invasiveness and number of procedures required for a successful treatment of choledocholithiasis.<sup>[4]</sup>

Common bile duct (CBD) stones are the most frequent indication for endoscopic retrograde cholangiopancreatography (ERCP) in clinical practice. Most CBD stones can be extracted with standard devices such as balloon and/or Dormia basket (DBE) following endoscopic sphincterotomy (ES). However, in approximately 15% of patients, clearance of the biliary tract cannot be obtained using standard techniques.<sup>[5,6]</sup> The term 'difficult stones' is used for stone size  $\geq 15$  mm in diameter, number of stones  $\geq 3$  especially if impacted in a not-dilated CBD and unusual shape or location (Mirizzi syndrome, intra-hepatic, proximal to strictures). In addition, distal CBD variants or stenosis, presence of periampullary diverticula (PAD) and altered anatomy due to previous biliary or gastrointestinal surgical procedures are further factors that can decrease the success rate of stone extraction.<sup>[5,6]</sup>

The aim of our study is to evaluate the efficacy and safety of therapeutic ERCP for 'difficult' biliary stones in elderly patients (85 years of age or older) in a single referral centre.

## MATERIALS AND METHODS

### Study design

From January 2015 to January 2017, data of patients undergoing therapeutic ERCP for CBD stones were retrospectively collected. The patients were divided into two groups based on their age: Group A (85 years old or older) and Group B (65 years old or younger). Patients were admitted to the hospital for upper abdominal pain, jaundice, altered pancreatic/liver enzymes and/or fever. All cases were radiologically evaluated with an abdominal ultrasound and/or magnetic resonance cholangiopancreatography. Pre-operative anaesthetic evaluation and American Society of Anesthesiologists (ASA) score assessment were carried out for all patients. Inclusion criteria were large ( $\geq 15$  mm) and/or multiple ( $\geq 3$ ) CBD stones, PAD, altered anatomy and unusual location of stone. Patients

with pancreaticobiliary malignancies were excluded from the study. Informed consent was obtained from all the participants.

### Procedure

ERCPs were performed with a standard side-viewing duodenoscope (Duodenoscope Olympus TJF160V-VR, Tokyo, Japan) after moderate sedation with midazolam and propofol in the case of  $\leq$ ASA2 or with general anaesthesia in the case of  $\geq$ ASA3. All procedures were performed with anaesthesiologic support. Anticoagulant/anti-aggregant therapies were managed according to the European Society of Gastrointestinal Endoscopy (ESGE) guidelines.<sup>[7]</sup>

Therapeutic approaches were ES plus DBE or partial ES (pES) plus endoscopic papillary balloon dilation (EPBD). The choice of the most appropriate approach was made during the procedure taking into consideration the diameter and number of the stones, CBD diameter, concomitant distal strictures, anatomy of the ampullary region and patient's medical history. If CBD clearance was not possible, a 10-Fr plastic stent was placed in order to guarantee biliary flow. Our attitude was to leave plastic stents in place for a maximum of 3 months and then perform a second-look endoscopy. All stones were extracted using a balloon catheter and/or DBE. Technical success was defined as complete clearance of the CBD with no residual stones at the end of the procedure.

Sedation safety and post-ERCP complications were defined and classified according to the ESGE guidelines.<sup>[8]</sup> Follow-up was conducted with abdominal ultrasound controls at 6 and 12 months; blood tests at 3, 6 and 12 months and/or telephone interview after 12 months.

### Statistical analysis

Distributions of quantitative variables were described as means ( $\pm$ standard deviation). Student's *t*-test was used to compare means. Qualitative variables were compared using the Chi-square test. Logistic regression was used for multivariate analysis.  $P < 0.05$  was considered statistically significant. All data were managed with Microsoft Excel version 2010, data analysis add-in, for Windows (Microsoft Corp, Redmond, WA, USA).

## RESULTS

### Study population

Two hundred and eighty patients aged above 85 years and 435 patients younger than 65 years underwent ERCP for biliary stones during the study period. The mean age of the patients in Group A was  $88.2 \pm 2.5$  years (range, 85–95 years) and that of patients

in Group B was  $50.4 \pm 10.8$  years (range, 19–65 years). ‘Difficult’ biliary stones were diagnosed in 110 patients among the elderly (39.2%; Group A) and in 62 cases among patients younger than 65 years old (14.2%; Group B). The total number of procedures was 134 in Group A and 69 in Group B. The main characteristics of both groups are described in Table 1. Comorbidities were statistically significantly higher in Group A compared to that of Group B (86.3% vs. 24.2%;  $P < 0.001$ ). Antithrombotic therapies were more common in Group A (48.2% vs. 19.3%;  $P < 0.001$ ). Similarly, ASA score was statistically significantly higher in Group A ( $P < 0.001$ ). A significantly higher number of patients from Group B underwent cholecystectomy during the same hospitalisation period (Group A 7/85 [8.2%] vs. Group B 22/52 [42.3%];  $P < 0.001$ ).

PAD was more frequently observed in Group A patients (38.1% vs. 17.7%;  $P < 0.006$ ). The therapeutic approaches were as follows: Group A – 59 (53.6%) patients underwent ES plus DBE and 51 (46.3%) patients underwent pES plus EPBD; Group B – 35 (56.4%) patients underwent ES plus DBE and 27 (43.5%) patients underwent pES plus EPBD. Papillary needle knife pre-cut was necessary in five patients in Group A and four patients in Group B (4.5% vs. 6.4%;  $P > 0.5$ ). No significant difference was found for mean stone size and CBD diameter among the groups (mean stone diameter in Group A:  $18.7 \pm 3.3$  mm vs. Group B:  $18.8 \pm 3.5$  mm,

$P > 0.8$ ; mean CBD diameter in Group A:  $20.4 \pm 3.2$  mm vs. Group B:  $21.3 \pm 3.5$  mm,  $P > 0.05$ ). The mean procedural time was  $26.8 \pm 5.5$  min versus  $27.3 \pm 7.4$  min for Group A and Group B, respectively ( $P > 0.6$ ) [Table 2].

### Need of re-intervention

Complete stone extraction was not possible at the first ERCP in 15 (13.6%) patients of Group A and 5 (8%) patients of Group B. In these patients, a 10Fr plastic biliary stent was delivered. No statistically significant difference between the two groups was detected ( $P > 0.2$ ). After an average of  $65 \pm 15$  days, these patients underwent a new ERCP for stent removal and re-evaluation.

In detail, 12 out of 15 patients from Group A had a second ERCP, with successful stone extraction in 8 of them. Three patients were lost to follow-up before re-evaluation. Four patients required a new biliary stent due to incomplete stone removal. In this subgroup, a third procedure was performed  $60 \pm 10$  days later with successful stone removal in two out of four cases. The remaining two patients presented with acute cholecystitis and cholangitis requiring laparoscopic cholecystectomy with surgical removal of CBD stones. In Group B, three out of five patients had a successful stone removal at second ERCP. One patient, with Billroth II reconstruction, had a duodenal perforation and consequently underwent emergency surgery. The remaining one patient was suffering from multiple left hepatic lobe stones associated with a non-dilatable left biliary duct

**Table 1: Main characteristics of patients in Group A and Group B**

n (%)	Group A (age >85, n=110)	Group B (age <65, n=62)	P
Age (years) (mean±SD)	88.2±2.5	50.4±10.8	<0.001
Sex (M/F)	51/59	28/34	n.s.
Concomitant Chronic Pathologies	95 (86.3)	15 (24.2)	<0.001
Cardiovascular diseases	65 (59)	11 (17.7)	
COPD/Asthma	19 (17.2)	3 (4.8)	
Neurological diseases	8 (7.2)	1 (1.6)	
Diabetes mellitus	21 (19.1)	6 (9.6)	
Renal diseases	2 (1.8)	0	
Hepatic diseases	2 (1.8)	1 (1.6)	
Previous Surgery			
Cholecystectomy	25 (22.7)	10 (16.1)	n.s.
Billroth II gastrectomy	6 (5.4)	2 (3.2)	n.s.
ERCP	6 (5.4)	2 (3.2)	n.s.
ASA Classification			<0.001
I	10 (9)	40 (64.5)	
II	62 (56.3)	19 (30.6)	
III	36 (32.7)	3 (4.8)	
IV	2 (1.8)	0	
Antithrombotic Therapy	53 (48.2)	12 (19.3)	<0.001
Aspirin	18 (16.3)	5 (8)	
Warfarin	3 (2.7)	0	
Clopidogrel	15 (13.6)	4 (6.4)	
Aspirin + Clopidogrel	8 (7.2)	1 (1.6)	
DOAC	9 (8.1)	2 (3.2)	
Cholecystectomy same admission	7/85 (8.2)	22/52 (42.3)	<0.001

SD: Standard Deviation; COPD: Chronic Obstructive Pulmonary Disease; ERCP: Endoscopic Retrograde CholangioPancreatography; ASA: American Society of Anesthesiologists; DOAC: Direct Oral Anticoagulants; n.s.: not significant.

**Table 2: ERCP outcomes in Group A and Group B**

n (%)	Group A (age >85) Patients n=110 Procedures n=134	Group B (age <65) Patients n=62 Procedures n=69	P
Success, overall (patients)	105 (95.4)	60 (96.7)	n.s.
First ERCP	95 (86.3)	57 (91.9)	n.s.
Needle Knife precut (patients)	5 (4.5)	4 (6.4)	n.s.
PAD (patients)	42 (38.1)	11 (17.7)	<0.006
Therapeutic approaches (patients)			n.s.
ES + BDE	59 (53.6)	35 (56.4)	
pES + EPBD	51 (46.3)	27 (43.5)	
Biliary stenting (patients)	15 (13.6)	5 (8)	n.s.
CBD diameter (mm) (mean±SD)	20.4±3.2	21.3±3.5	n.s.
Stones diameter (mm) (mean±SD)	18.7±3.3	18.8±3.5	n.s.
Procedure time (min) (mean±SD)	26.8±5.5	27.3±7.4	n.s.
Midazolam dosage (mg) (mean±SD)	2.8±0.7	2.93±0.9	n.s.
Propofol dosage (mg) (mean±SD)	148.2±36.15	174.6±42.4	<0.001
Need for surgery (patients)	2 (1.8)	2 (3.2)	n.s.
Hospitalization stay (days) (mean±SD)	3.3±1.3	4±1.7	<0.005

ERCP: Endoscopic Retrograde Cholangiopancreatography; PAD: Periapillary diverticula; ES: Endoscopic Sphincterotomy; BDE: Balloon Dormia Extraction; pES: partial Endoscopic Sphincterotomy; EPBD: Endoscopic Papillary Balloon Dilation; CBD: Common Bile Duct; SD: Standard Deviation; n.s.: not significant.

stenosis. Considering his age, the presence of parenchymal atrophy and the unilobar left-sided hepatolithiasis, it was decided to proceed with surgery, performing a left hepatectomy. Both patients recovered well. There was no statistically significant difference between the two groups regarding the need for surgery (Group A – 1.8% vs. Group B – 3.2%;  $P > 0.5$ ).

### Complication rate

Complications occurred in 11 (8.2%) cases in Group A and in nine (13%) cases in Group B without statistically significant differences among the groups ( $P > 0.2$ ) [Table 3]. The most common complication was pancreatitis (Group A – 2.2% vs. Group B – 5.7%;  $P > 0.1$ ). Almost all cases were classified as mild. Only one patient (Group B) suffered from moderate pancreatitis, which was treated with conservative therapy. Although antithrombotic therapies were more frequent in Group A, no differences in post-procedural bleeding were found between the groups (Group A – 1.49% vs. Group B – 2.89%;  $P > 0.4$ ). Cholecystitis/cholangitis was observed in three patients in Group A and one patient in Group B (Group A – 2.2% vs. Group B – 1.4%;  $P > 0.7$ ). No procedure-related deaths occurred.

### Sedation

A total of 72 patients from Group A and 59 patients from Group B underwent the procedures under moderate sedation with midazolam and propofol. No statistically significant difference regarding the mean dose of midazolam was observed between the two groups (Group A –  $2.8 \pm 0.7$  mg vs. Group B –  $2.93 \pm 0.9$  mg;  $P > 0.3$ ). The elderly group received a lower mean dose of propofol than that of the control group (Group A –  $148.2 \pm 36.15$  mg vs. Group B –  $174.6 \pm 42.4$  mg;  $P < 0.001$ ). Sedation-related adverse events were detected

**Table 3: Complications**

n (%)	Group A (age >85) procedures n=134	Group B (age <65) procedures n=69	P
Overall	11 (8.2)	9 (13)	n.s.
Pancreatitis, overall	3 (2.2)	4 (5.7)	n.s.
Mild	3 (2.2)	3 (4.3)	
Moderate	0	1 (1.4)	
Bleeding	2 (1.49)	2 (2.8)	n.s.
Cholangitis/Cholecystitis	3 (2.2)	1 (1.4)	n.s.
Perforation	0	1 (1.4)	n.s.
Sedation adverse events*	3/72 (4.1)	1/59 (1.6)	n.s.
30-days mortality	0	0	

\*Only procedures performed under moderate sedation; n.s.: not significant.

in three patients in Group A and one patient in Group B, without statistically significant difference among the groups (Group A – 4.1% vs. Group B – 1.6%;  $P > 0.4$ ). The most common complications were hypoxaemia and hypotension with the need of temporary suspension of the examination. After adequate anaesthesiologic support, a new procedure was performed successfully. No cases of post-operative delirium or post-operative cognitive dysfunction were observed.

### Overall results and recurrence

The overall success rate was 95.4% and 96.7% in Group A and Group B, respectively. During the follow-up period, a total of 165 patients (105 from Group A vs. 60 from Group B) were evaluated for a mean time of  $33.6 \pm 5.9$  months [Table 4]. Seven patients were lost at follow-up. During the 2<sup>nd</sup> year of follow-up, five patients from Group A and one patient from Group B died from unrelated causes without symptoms of recurrent biliary stones. Eight patients from Group A and three patients from Group B presented recurrence of CBD stones (Group A – 7.6% vs. Group B – 5%;  $P > 0.5$ ). In 6/11 patients (54.5%), recurrence occurred within

**Table 4: Follow-up data**

n (%)	Group A (age >85) Patients n=105	Group B (age <65) Patients n=60	P
Time of follow-up (months)(mean±SD)	33.2±6.3	34.2±5.1	n.s.
Recurrence of choledocolithiasis	8 (7.6)	3 (5)	n.s.
Recurrence of choledocolithiasis in patients with intact gallbladder	5/74 (6.7)	2/29 (6.8)	pA n.s.*; pB n.s.*
Died due to unrelated causes	5 (4.7)	1 (1.6)	n.s.

n.s.: not significant; SD: Standard Deviation; \* In comparison to patients with previous cholecystectomy of each group

**Table 5: Multivariate analysis of risk factors for recurrence in Group A**

Variables	Odds Ratio	95% CI	P
Periampullary Diverticula	12.9	0.44-4.66	0.01

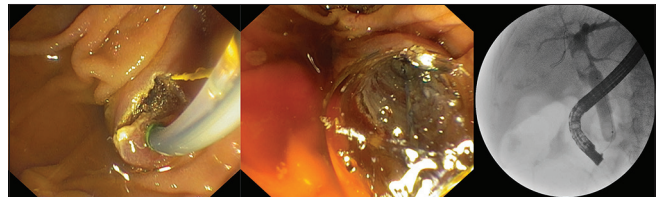
CI: Confidence Interval

the first 2 years. All patients underwent ERCP and were successfully treated with either ‘recut’ or EPBD.<sup>[9]</sup> The Kaplan–Meier analysis showed no difference among the two groups regarding the time of recurrence (log rank  $P > 0.4$ ). In Group A, recurrence of CBD stones was detected in 5/74 (6.7%) patients with an intact gallbladder and in 3/31 (9.6%) patients with previous cholecystectomy ( $P > 0.6$ ). In Group B, the corresponding values were 2/29 (6.8%) and 1/31 (3.2%) ( $P > 0.5$ ), respectively. The multivariate analysis showed no correlation between recurrent choledocholithiasis and previous cholecystectomy, stone/CBD diameter and type of therapeutic approach. Interestingly, a significant correlation was found among recurrence and presence of PAD ( $P < 0.02$ ) [Table 5].

## DISCUSSION

Our study evaluated the efficacy and safety of ERCP procedure in elderly population with ‘difficult’ stones, comparing the outcomes with a group of younger patients. Endoscopic treatment of biliary stones is considered the ‘gold standard’ approach, especially in older patients that are burdened with higher risk of surgical complications. From our data, it appears that the incidence of complex biliary stones is much higher in elderly patients than that in younger ones (Group A – 39.2% vs. Group B – 14.2%;  $P < 0.001$ ). Several factors may contribute to such higher incidence. First, surgical altered anatomy is more common in patients with advanced age. Second, the prevalence of PAD increases with age and PAD itself seems to be an important contributing factor for CBD stones.<sup>[10,11]</sup> Moreover, malnutrition state, dehydration and drug poly-therapies may contribute to biliary stasis, infections (e.g., cholangitis) and thus to biliary stone formation.<sup>[12]</sup>

Our results confirmed that the efficacy and safety of ERCP in elderly is comparable to that in the



**Figure 1: pES + EPBD for large common bile duct stone. pES + EPBD: Partial sphincterotomy plus endoscopic papillary balloon dilation**

control group. Both groups showed high technical success rates (Group A – 95.4% vs. Group B – 96.7%). Importantly, 86.3% of the Group A patients and 91.9% of the Group B patients, needed only one procedure. In addition, the need for surgery rate was very low in both groups (Group A – 1.8% vs. Group B – 3.2%). In our experience, pES + EPBD [Figure 1] was found to be efficient and safe, especially in patients under antithrombotic therapies and with the presence of PAD. Complete ES in these cases could lead to complications such as bleeding and perforation. pES + EPBD attains a simultaneous dilation of the distal part of CBD that facilitates the *en bloc* removal of large stones. This technique reduces both the need of mechanical lithotripsy and the risk of recurrence due to residual minute fragments that could act as core for new stone formation. Similar observations have been reported in other studies.<sup>[13,14]</sup>

If stone clearance was not achieved, a plastic stent was inserted in the CBD in order to guarantee bile flux, as international guidelines recommend.<sup>[15]</sup> Several studies reported that biliary stents were used more frequently in elderly population.<sup>[16,17]</sup> However, in our study, there was no difference, regarding the need for biliary stenting among the two groups (Group A – 13.6% vs. Group B – 8%;  $P > 0.2$ ).

The incidence of ERCP-related adverse events has been reported to be as high as 10%.<sup>[18-20]</sup> In our study, the overall complication rate was 8.2% for Group A and 13% for Group B. The slightly higher incidence of complications could be explained by the fact that only complex biliary stones have been included.

Post-ERCP pancreatitis is the most frequent and severe complication with incidence and mortality rates of 3.5%–9.7% and 0.1%–0.7%, respectively.<sup>[19]</sup> Some studies

suggest that pancreatitis is less frequent in the elderly.<sup>[19,20]</sup> Lukens *et al.*<sup>[18]</sup> reported a pancreatitis rate of 0.14% in elderly population, suggesting that increased age may be a protective factor. Pancreatitis was the most common complication in our study too; however, no statistically significant difference was found between the two groups (Group A – 2.2% vs. Group B – 5.7%;  $P > 0.1$ ). Only one case of moderate pancreatitis was detected in Group B, and all the other cases were diagnosed as mild. All patients were successfully treated with conservative therapy.

The second-most common complication is post-procedural bleeding, with an incidence ranging from 0.3% to 9.6%.<sup>[8]</sup> Antithrombotic therapies, coagulopathies, thrombocytopenia, intraprocedural bleeding and pre-cut sphincterotomy have been described as the possible risk factors.

In our series, no differences were found among the two groups (Group A – 1.49% vs. Group B – 2.89%;  $P > 0.4$ ). Although in the present study elderly patients used antithrombotic agents more frequently, all antithrombotic therapies were managed according to the ESGE guidelines and when possible, pES + EPBD was preferred over complete ES in order to minimise the risk of bleeding. Previous studies showed a similar trend.<sup>[16,22]</sup>

Sedation-related adverse events are frequent with a reported incidence as high as 24.6%.<sup>[8]</sup> However, these events are generally intraprocedural, mild and transitory, without major repercussions on treatment strategy. Hypoxaemia and hypotension represent the most frequent complications, especially in the elderly undergoing ERCP.<sup>[23]</sup> Propofol-based sedation has been reported to be safe for high-risk patients.<sup>[24]</sup> However, a recent randomised controlled trial<sup>[25]</sup> has suggested that general anaesthesia is preferable to moderate sedation in high-risk patients undergoing ERCP. Although no significant differences in sedation-related complications were detected between the two groups, we believe that the availability of anaesthesiologists is crucial for the safety of the patients undergoing ERCP.

In recent studies, the recurrence rate of biliary stones after ERCP has been reported as high as 12.4%.<sup>[21,26]</sup> We reported an overall recurrence rate of 7.6% for Group A and 5% for Group B ( $P > 0.5$ ). Several factors have been evaluated as the predictors for recurrence. However, only CBD diameter and PAD have been confirmed as independent risk factors.<sup>[21,26]</sup> There is no unanimously defined CBD diameter predicting recurrence and its threshold varies from 15 to 22 mm. In our study, no correlation between CBD diameter and recurrence was

found. This could be explained by the fact that in our study CBD dilation was already present at index ERCP. On the other hand, multivariate analysis confirmed that PAD was an independent risk factor for recurrence of CBD stones. The presence of PAD modifies the anatomy of the papilla, the distal CBD and the pancreatic duct. These modifications along with food deposits, intradiverticular bacteria overgrowth and Oddi's sphincter dysfunction may cause bile stasis, duodenal–biliary reflux and infections, even after ES.<sup>[10]</sup>

Finally, our data showed that younger patients presented statistically significantly longer mean hospitalisation stay (Group A –  $3.3 \pm 1.3$  days vs. Group B –  $4 \pm 1.7$  days;  $P < 0.005$ ). This finding could be easily justified as more individuals in the control group underwent cholecystectomy during the same admission. It is not yet clear if cholecystectomy in the elderly is beneficial after ES and bile duct clearance. A Cochrane review in 2007<sup>[27]</sup> reported that prophylactic cholecystectomy is superior to 'watch-and-wait' approach in terms of morbidity and mortality rates. However, other studies suggested that cholecystectomy after ES was not necessary in the elderly as the cumulative morbidity and mortality rates were low and the surgical risks were high.<sup>[28,29]</sup> Similarly, in our study, no difference was found among the elderly with and without previous cholecystectomy regarding the recurrence of CBD stones (6.7% with intact gallbladder vs. 9.6% with previous cholecystectomy;  $P > 0.6$ ).

This study had some limitations. First, our study was limited by its retrospective nature and by the fact that it was performed at a single centre and consequently, selection bias cannot be excluded. Moreover, the sample in the control group was limited due to lower prevalence of 'difficult' biliary stones in younger patients. Second, the patient's risk assessment was evaluated only with the ASA score and the anaesthesiologist was not always the same. Third, all the procedures were performed in an elective setting and hence the results cannot be extended to the emergency setting. Moreover, the outcomes of this study cannot be generalised because our centre is a high-volume, tertiary academic centre with highly skilled endoscopists. However, to our knowledge, this is the first study that has been focussed on the efficacy and safety of endoscopic therapy in elderly patients with solely 'difficult' biliary stones, providing also follow-up data.

## CONCLUSION

Our outcomes demonstrate that therapeutic ERCP in the very elderly (>85 years) with 'difficult' biliary stones

is a safe and highly effective procedure. No significant differences were found in comparison with the control group (<65 years), regarding the success and complication rates. Follow-up data suggest that late biliary complications are similar in both groups. According to our study, age should not represent a barrier to ERCP, provided that an accurate pre-operative evaluation has been performed and an experienced endoscopic/anaesthesiologic/surgical team is available.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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